I. The Office Action

The December 22, 2006 final-Office Action (the "Office Action") in this application:

1.) maintained its rejection of claims 7-11 under 35 U.S.C. 102(b);

2.) maintained its rejection of claims 1-11, 13-19 and new claim 20 under 35 U.S.C. 112, first paragraph;

3.) maintained its rejection of claims 7-11 under 35 U.S.C. 102(b);

4.) rejected claims 4, 10 and 18 under U.S.C. 112, first paragraph; and

5.) rejected claim 20 under 35 U.S.C. 103(a).

Applicant responds as follows.

II. Amendments, cancellation of claims and new claim 21

Claims 2-4, 7-11, 16-18 and 20 are hereby cancelled without prejudice or disclaimer to further prosecution at a later date.

Support for botulinum toxin "type A" in all amended independent claims can be found throughout the specification, such as, for example, at page 23, lines 1-2 of the specification and original claims 3 and 9.

Support for the recitation of a pressure sore located at "a buttocks area or heel" in claim 6 can be found at least at page 1, lines 27-28 and page 44, line 29 of the specification.

Support for "debriding the pressure sore" in claim 13, can be found at least at page 44, line 10 of the specification.

Support for "intradermally administered as about 1 unit/cm^2" in new claim 21 can be found at least at page 43, line 5 of the specification.

III. Rejection of claims 7-11 under 35 U.S.C. 102(b)

The Office Action maintains its rejection of claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Gassner et al. (U.S. Patent 6,447,787). Applicant respectfully traverses this rejection.

Applicant maintains that the Gassner et al. reference is directed to the treatment of skin lacerations and incisions (Gassner et al., col. 3 lines 6-20) and more particularly, to the minimization of resulting scar tissue formation, by minimizing the effects of muscle tension and movement on a wound (Gassner et al., col. 3 lines 37-40), and is not related to the treatment or prevention of pressure sores or administration of botulinum toxin to pressure points.

As previously submitted, the Office Action continues to misconstrue the term "unfavorable wound", as defined in Gassner et al., which is *not* a region of inflamed skin that needs wound healing, as stated by the Office Action, but is instead a wound that is oriented relatively perpendicularly to a relaxed skin tension lines (RSTL) (see Gassner et al., col. 3, lines 16-18). Such clear disclosure provides further evidence that Gassner et al. teaches the use of botulinum toxin for treating skin lacerations and incisions, and not pressure sores, as presently claimed.

However and solely to further prosecution, claims 7-11 are cancelled, without prejudice or disclaimer, to further prosecution at a later date, which renders this rejection moot.

Thus, the rejection should be withdrawn.

VI. Rejection of claims 1-11, 13-19 and 20 under 35 U.S.C. 112, first paragraph

The Office Action maintains its rejection of claims 1-11, 13-19 and rejects 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

As noted above, all pending claims now positively recited use of botulinum toxin type A in the claimed methods for treating a pressure sore (Claims 1, 5, 6, 13-15 and 19 remain pending upon entry of this amendment). The Office Action asserts that the breadth of the previously pending claims 4, 10 and 18 renders the claims nonenabled. Respectfully, this is improper. The contemplation of inoperative embodiments (*i.e. the administration of a lethal dose of botulinum toxin*), which fall within the scope of a claim, is not an indication of nonenablement. The claims are not directed to inoperative embodiments, but rather to a method for *treating a pressure sore*, not administering a lethal dose of a botulinum toxin, such as type A, which is clearly not a method of treating a pressure sore.

Indeed and as evidenced by the Office Action's assertion itself, it is apparently clear that one of ordinary skill in the art would not contemplate or consider the administration of a lethal dose of botulinum toxin as a method for treating a pressure sore. The Office Action is respectfully reminded that claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. In re Skrivan, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970), i.e. Applicant respectfully submits that it would be obvious to one of ordinary skill in the art that administration of a lethal dose of a botulinum toxin, such as type A, would not be considered or contemplated as a method for treating a pressure sore and, accordingly, one of ordinary skill in the art would instead administer therapeutically effective amounts of botulinum toxin type A, as presently claimed.

Furthermore, one of ordinary skill in the art, knowing what has come before and having the instant specification in hand, is clearly enabled to fully practice the instantly claimed methods, including administering a therapeutically effective amount of a botulinum toxin type A to or in the vicinity of a pressure sore, in an amount that does not paralyze a muscle. As known in the art, administration of a therapeutic is not fixed, as effective doses typically depend on several factors, such as, for example, the severity of the pressure sore, size, weight, and responsiveness of a patient to therapy (all typical medical parameters known to those of skill in the art), such that the amount of toxin administered can vary (see page 34 of the specification, as an example). Recall that it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation (MPEP 2164.01(c)). Such determinations are standard in the medical arts and are made on a case by case basis (page 40, lines 16-29 of the instant specification).

Recall "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984), emphasis ours. One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977).

To limit the inventors to only specific exemplary aspects of their invention is contrary to the explicit purpose of the patent system. In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials

in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

However and solely to facilitate prosecution, pending claims 1, 5, 6, 13-15 and 19 have been amended to recite administration of therapeutically effective amounts of botulinum toxin type A, wherein the amount is less than the amount used to paralyze a muscle and claims 4, 8 and 18 have been cancelled. As noted above, a therapeutically effective amount is not a fixed amount and will vary on a case by case basis, but is, however within the purview of one of ordinary skill in the art, in light of the over two decades of use of botulinum toxin type A in various clinical settings to treat various maladies and the instant specification.

Thus, this rejection should be withdrawn.

V. Rejection of claims 7-11 under 35 U.S.C. 102(b)

The Office Action rejected claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Borodic (US 2002/0187164). Applicant traverses the rejection, as Borodic is not directed to wound treatment, let alone treatment of pressure sores.

As stated above, claims 7-11 are cancelled without prejudice or disclaimer, thus obviating this rejection.

Thus, this rejection should be withdrawn.

VII. Rejection of claims 4, 10 and 18 under U.S.C. 112, first paragraph

The Office Action rejected claims 4, 10 and 18 under U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 4, 10 and 18 have been cancelled without prejudice or disclaimer and thus this rejection is moot.

Thus, the rejection should be withdrawn.

VIII. Rejection of claim 20 under 35 U.S.C. 103(a)

The Office Action has rejected claim 20 under 35 U.S.C. 103(a) as being unpatentable over Rebar et al. (US 2003/0021776) in view of Borodic (US 2002/0187164).

Claim 20 has been cancelled, thus this rejection should be withdrawn.

IX. Conclusion

All issues raised in the Office Action have been addressed and the claims are in condition for allowance. Reconsideration and allowance of claims 1, 5-6, 13-15, 19 and 21 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/CLAUDE L. NASSIF/

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